Amendment dated: December 23, 2009 Reply to Office Action of Oct. 10, 2009

### **REMARKS / ARGUMENTS**

This is in response to the final Office Action mailed on October 10, 2009. No new matter is being added by the amendments made herein. Entry of this Response is respectfully requested.

Applicants firstly wish to truly thank Examiner Harris for withdrawing the finality of the previous Office Action of December 3, 2008 pursuant to our mutual discussions.

## 1) Claim Amendments and Support for Newly Presented Claims

Claims 11 and 26 have been amended to specify that the recited p75 polypeptide is produced by translation initiation in exon 21 of the CDP/Cux gene. In that regard, the Examiner is respectfully referred to the attached "Figure A", which is submitted merely for illustrative purposes and is intended only to aid the Examiner's understanding of the present amendment, should the Examiner find it helpful. Figure A is a schematic representation which shows: (1) the relevant part of the CDP/Cux gene; (2) the "I20-mRNA" that encodes p75; and (3) the p75 polypeptide produced by translation initiation in exon 21 (shown in yellow). Also shown are the relative positions of introns 20-23, exons 20-24, the start ("p75 AUG") and stop ("p75 stop") codons of p75, as well as the relative positions of transcription and translation initiation. As depicted in Figure A, the "I20-mRNA" molecule (2) is produced by transcription initiation in Intron 20 while the p75 polypeptide (3) is produced by translation initiation in exon 21.

Support for this amendment can be found throughout the application as filed, for example, in the paragraph spanning pages 6-7 and, more particularly, by the phrase "The I20-mRNA contains a long 5'-untranslated sequence followed by **an open reading frame** starting at the beginning of exon 21" (first sentence of the paragraph) [emphasis added].

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Applicant respectfully submits that the skilled person will understand from the above recitation that the p75 polypeptide is produced by translation initiation in exon 21 of the CDP/Cux gene, and that translation of p75 is in the same frame as that of p200.

#### 2) Claim Rejections - 35 U.S.C. § 102

The Examiner has rejected **claim 11** under 35 U.S.C. § 102(b) as allegedly being anticipated by Moon 2001 (Moon et al., Molecular and Cellular Biology 21(18): 6332:6345, September 2001).

The Examiner has also rejected **claim 26** under 35 U.S.C. § 102(a) as allegedly being anticipated by Moon 2002 (Moon et al., Int. J. Cancer 100:429-432, August 2002).

More particularly, the Examiner appears to argue that because the antibodies of Moon 2001 or Moon 2002 recognized other isoforms of CDP/Cux, these same antibodies would recognize "the p75 polypeptide within the full length protein". For the record, Applicant disagrees that either Moon 2001 or Moon 2002 previously disclosed p75, as the existence of p75 was not known prior to the present invention. However, please note that claims 11 and 26 have been amended to specify that the recited p75 polypeptide **is produced by translation initiation in exon 21 of the CDP/Cux gene**. Of course, none of the cited references alone or in combination teach an association between p75 and cancer. In that regard, Applicant respectfully submits that neither Moon 2001 nor Moon 2002 teach or suggest a p75 polypeptide produced in this fashion. It follows that the two Moon references not having taught (or suggested) p75 initiating in exon 21 could not teach (or suggest) that the presence of p75 is associated with breast cancer or AML. In view of the above, Applicant respectfully submits that Moon 2001 or Moon 2002 cannot be considered as anticipating claim 11 or claim 26.

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In view of the foregoing, Applicant respectfully submits that claims 11 and 26 fully comply with 35 U.S.C. § 102(a) and 102(b). Withdrawal of these objections is thus respectfully requested.

## 3) Claim Rejections - 35 U.S.C. § 103(a)

The Examiner has rejected **claims 11, 16-19, 26 and 27** under 35 U.S.C. 103(a) as allegedly being obvious in view of the combination of either Moon 2001 or Moon 2002 and Nepveu (Gene 270: 1-5, 2001). First, Applicant concurs with the Examiner that neither Moon 2001 nor Moon 2002 teach the disclosed method of detection wherein the sample tested is derived from blood or breast tissue and said detection methodology is comprised within a kit. Second, the Examiner is respectfully referred to the remarks presented above regarding the amendments to claims 11 and 26. Applicant respectfully submits that neither Moon 2001, Moon 2002, nor Nepveu, either alone or in combination, teach or suggest a p75 polypeptide **produced by translation initiation in exon 21 of the CDP/Cux gene**. Of course, none of the cited references alone or in combination teach an association between p75 and cancer. Thus, Applicant respectfully submits that claims 11 and 26 cannot be considered obvious in view of the cited prior art, and that claims 16-19 and 27 are also non-obvious by way of their direct or indirect dependence on either claim 11 or 26.

In view of the foregoing, Applicant respectfully submits that claims 11, 16-19, 26 and 27 fully comply with 35 U.S.C. 103(a). Withdrawal of these objections is thus respectfully requested.

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## 4) CONCLUDING REMARKS

In view of the above, it is respectfully submitted that the application and claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the telephone number shown below.

No fee is believed to be required to enter this response. However, should a fee be necessary, please charge Deposit Account No. 07-1742.

Respectfully submitted,

Date: December 23, 2009

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# Figure A: Schematic representation of "120-mRNA" and p75 p75 STOP Exon 24 Intron 23 Exon 23 Intron 22 **Exon 22 Exon 23** Translation initiation Exon 22 445 aa Intron 21 in Exon 21 Intron 20/Exon 21 junction 3389 nt Exon 21 Exon 21 p75 AUG (3) p75 protein Transcription initiation Intron 20 (2) I20-mRNA encoding p75 Exon 20 (1) CDP/Cux gene